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IN THE

Supreme Court of the United States

October Term, 1965

No. 495

An Undetermined Number of Shipping Packages, Etc.

VITASAFE CORPORATION,

Petitioner,

AGAINST

UNITED STATES OF AMERICA,

Respondent.

VITASAFE CORPORATION, A Corporation, NUTRITIONAL QUALITY CONTROLS, INC., A Corporation, THE DOLLAR VITAMINE PLAN, INC., A Corporation, LIFE NUTRITION, INC., A Corporation, INTERNATIONAL OIL AND METALS CORPORATION, A Corporation, DR. PARKER MEDICINE COMPANY, A Corporation, PHILIP S. VOLOSOV, An Individual and HENRY D. COHEN, An Individual,

Petitioners,

AGAINST

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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INDEX

	PAGE
Citations to Opinions Below	2
Jurisdiction	2
Questions Presented	2
Statutes and Regulations Involved	3
Statement	3
Reasons for Granting the Writ	4
Conclusion	11
APPENDIX A:	
Opinion	13
Amendment to Opinion Filed January 24, 1964	39
Memorandum Opinion	41
Opinion of the Court	50
Judgment	64
APPENDIX B:	
Statutes	67
Regulations	71
APPENDIX C:	
United States v. Unknown Quantities . . . Honegar, Etc.	72
Memorandum Decision	73

CASES CITED

	PAGE
Hygrade Foods Products Corp. v. United States, 160 F. 2d 816 (CA 8, 1947)	5
Mandell, William B., 332 F. 2d 286 (Third Circuit 1964)	10
United States v. Unknown Quantities of An Article of Drug * * * Honegar * * * United States District Court, Northern District of New York (unreported)	5
United States v. 119 Cases * * * New Dextra Brand Fortified Cane Sugar, 231 F. Supp. 551, affd., 334 F. 2d 238 (C. A. 5, 1964)	5, 6, 9
U. S. A. v. Various Articles of Drugs * * * Kaybel, Inc., United States District Court, District of New Jersey, (1963) (unreported)	10
U. S. A. v. Various Articles of Drug * * * Stanack Sales Co., Inc., U. S. District Court of New Jersey, (1963) (unreported)	9, 10

STATUTES CITED

28 U. S. C. 1254(1)	2
Federal Food, Drug and Cosmetic Act:	
Section 301 [21 U. S. C. 331]	3, 4
Section 302(a) [21 U. S. C. 332(a)]	2, 3, 4
21 U. S. C. 343(j)	2

PAGE

Section 403(a) [21 U. S. C. 343(a)] 3

Section 403(i) [21 U. S. C. 343(i)] 3, 8

Section 403(j) [21 U. S. C. 343(j)] 3, 8

Section 502(a) [21 U. S. C. 352(a)] 3

Section 502(f)(1) [21 U. S. C. 352(f)(1)] 3, 10

Title 21 Code of Federal Regulations:

Section 125.3(a)(2) 3

Section 125.3 8

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Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit, entered in the above entitled cases on May 27, 1965.

Citations to Opinions Below

The opinions of the District Court are printed in Appendix A, *infra*, pages 13 and 41, and are officially reported at 226 F. Supp. 266 (1964) and 235 F. Supp. 84 (1964).

The opinion of the Court of Appeals, on a consolidated appeal, is printed in Appendix A, *infra*, page 50, and is officially reported at 345 F. 2d 864 (1965).

Jurisdiction

The judgment of the Court of Appeals was entered on May 27, 1965 (Appendix A, *infra*, page 64). The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

Questions Presented

1. Whether Section 302(a) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 332(a)] authorizes the issuance of a punitive injunction to enjoin the shipment of a product, with proper labeling, to anyone who previously became a customer in response to an advertisement which contained a false or misleading statement.

2. Whether the Federal Food, Drug and Cosmetic Act, (21 U. S. C. 343(j) authorizes the prohibition of the sale of dietary supplements and food products, or whether it solely requires the presentation of all material facts.

3. Whether a truthful statement of a product's value can be prohibited because of its alleged benefit to a "small" number of individuals.

4. Whether an erroneous statement not related to the nature, composition, proper use or value of the product constitutes misbranding under the Federal Food, Drug and Cosmetic Act.

5. Whether the words "lipotropic factors" constitute a representation of treatment of liver diseases to the average individual.

Statutes and Regulations Involved

The statutory provisions involved are Sections 301, 302(a), 403(a), 403(i), 403(j), 502(a), and 502(f)(1) of the Federal Foods, Drug and Cosmetic Act [21 U. S. C. 331, 332(a), 343(a), 343(i), 343(j), 352(a) and 352(f)(1)] and Title 21 Code of Federal Regulations, Section 125.3(a)(2). They are printed in Appendix B, *infra*, page 67.

Statement

An *in rem* seizure action and an injunction action were brought, under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 301 *et seq.*, alleging that various vitamin and mineral products are misbranded under 21 U. S. C. 343(a), 352(a) and 352(f)(1). It is charged that the labeling for said products contains false or misleading representations and that the said labeling does not bear adequate directions for use.

The District Court held that the articles were misbranded as alleged in the libel and further issued an in-

junction which enjoins the making of various representations for said products; the sale of the products to any customer who previously purchased the products; and which further contains a provision that constitutes an absolute prohibition against the sale of the products irrespective of its labeling. Said rulings contain prohibitions affecting the freedom of sale and the freedom of purchase of dietary supplement products.

The Court of Appeals affirmed the judgment and order of the District Court, with certain modifications which are not relevant to the questions presented herein.

Reasons for Granting the Writ

Petitioners respectfully submit that certiorari should be granted herein to resolve a difference in rulings between two different Circuits upon a basic question of industry regulation under the Federal Food, Drug and Cosmetic Act.

There are further presented herein a number of recurring questions of statutory construction having broad applicability to the food, drug and cosmetic industry. They include absolute prohibitions involving the sale of vitamin products which were not intended by Congress and are not authorized by Statute.

1. Petitioners respectfully submit that the Federal Food, Drug and Cosmetic Act does not authorize an injunction to prohibit the shipment of a product, with proper labeling, on the ground that prior literature contained a false and misleading statement. Section 302(a) of the Statute grants jurisdiction to the District Courts of the United States to restrain certain specified violations of Section 301 of said Statute.

The injunction issued below is punitive in nature. It does not enjoin a future violation of the Act. It punishes the company for a past violation. The Courts below exceeded their statutory power and have created the present reality whereby a company can be completely destroyed and put out of business at any time that it has a false or misleading statement in its labeling material. The issue is whether a product can be sold with proper labeling after a prior error or whether the product becomes forever tainted.

The broad and sweeping injunction issued herein could not possibly be complied with as a practical matter and is further in conflict with the rulings in *Hygrade Food Products Corp.* v. *United States,* 160 F. 2d 816, (CA 8, 1947), and *United States* v. *Unknown Quantities of An Article of Drug* * * * *Honegar* * * * in the United States District Court, Northern District of New York (unreported) (A copy of said decision is included in Appendix C herein, *infra,* page 72).

2. Petitioners further submit that there is a direct conflict in rulings between two Circuits in the ruling of the Court of Appeals in the instant case and the ruling of the Court of Appeals for the Fifth Circuit in *United States* v. *119 Cases* * * * *New Dextra Brand Fortified Cane Sugar,* 231 F. Supp. 551, affd., 334 F. 2d 238 (C. A. 5, 1964). In the instant case and in the *Dextra* case, the Government attempted to apply a concept of a so-called "average American diet" as a basis for misbranding the sale of foods and dietary supplement products.

Thus, in the instant case, the petitioners set forth in their labeling various symptoms which are caused by a deficiency of the specific vitamins and minerals contained in the product. The lower Court held that these state-

ments constitute false representations by reason of the fact that the likelihood of such symptoms being caused by vitamin and mineral deficiency in the United States is very small.* The lower Court's ruling, affirmed by the Court of Appeals, is premised upon the Government's argument that there is a so-called "average American diet" which contains all the vitamins and minerals that we need.

The very use of the concept of an average American diet presupposes that there are approximately the same number of persons who receive less than the average American diet as those who receive more than this so-called average. This same contention was considered in *United States* v. * * * *119 Cases* * * * *Dextra, supra,* and the District Court, affirmed by the Court of Appeals, held that the concept of an average American diet is not proper for the purposes of misbranding a product. The Court stated that the use of an average implies that some persons may be getting more nutrients and others less, and that such broad measures of nutritional adequacy bear little relationship to the needs of any single individual or groups of individuals. The Court also found that the diet of a small but significant portion of our population is deficient in vitamins.

The ruling in the instant case involves a basic concept of industry regulation in which two Circuits have now differed. This difference should be resolved in the interest of the entire food, drug and cosmetic industry.

The Lower Court's ruling also raises the question as to whether the purpose and intent of the Food, Drug and

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* It may be noted that petitioners made a specific statement in their literature to the effect that the symptoms may result from a great number of other causes.

Cosmetic Act is to require the furnishing of relevant and truthful information to the consumer or whether it can be used as a regulatory tool to invoke broad prohibitions against the marketing of products with factual representations, truthfully presented.

The food and drug industry is also faced with a conflict in position between the Food and Drug Administration and the Federal Trade Commission upon the precise question herein. The Federal Trade Commission has ruled that a statement of symptoms related to vitamin-mineral deficiencies must be joined with proper statements advising that such symptoms are caused by many other conditions as well as by a vitamin or mineral deficiency. The Food and Drug Administration, on the other hand, has requested and herein obtained a ruling prohibiting any statements or representations of symptoms related to vitamin-mineral deficiencies.

3. Petitioners further submit that there is an issue presented herein not only as to the prohibition of factual representations in the sale of products, but actually as to the prohibition of the sale of products themselves.

There is a serious question of statutory construction involving the use of the Statute as a tool to prohibit the sale of products rather than to regulate their sale with proper labeling. Thus, the District Court effectively ruled, and affirmed by the Court of Appeals, that the petitioners cannot sell their vitamin and mineral products because various ingredients have not been established as essential in human nutrition.

The petitioners are selling vitamin and mineral products as dietary supplements. They are made up of a number

of ingredients, all of which are found in various foods. Some of the ingredients have heretofore been found to be necessary in human nutrition. Other food ingredients have not been established, as of the present time, as essential or necessary in human nutrition.

Section 403(j) of the Federal Food, Drug and Cosmetic Act and Regulation 21 CFR Section 125.3 relate to the sale of dietary supplements and provide in relevant part:

> "If the need in human nutrition for such vitamin has not been established, the label shall also bear the statement: 'The need for * * * in human nutrition has not been established,' the blank to be filled in with such vitamin."

The Statute further requires the listing of all ingredients on the label* and as above indicated, requires a proper informational statement as to whether the need has been established or has not been established for the particular ingredient.

The Statute is clear in its purpose to require the giving of relevant information. In the instant case, the Court has ruled that the mere listing of the ingredients, for which no need has been established, constitutes misbranding. Thus, if the petitioners comply with the Statute and regulations, in listing all ingredients and in setting forth the required information with respect to each ingredient, the product under the instant ruling would be misbranded and could not be shipped.

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*Section 403(i) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 343(i)].

Petitioners submit that the Courts below have attempted to legislate by Court decree. A similar attempt was made by the Government in *United States of America* v. * * * *119 Cases* * * * *Dextra, supra,* where the Court stated:

> "The basic flaw in the Government's case against the product is that it is seeking, under the guise of misbranding charges, to prohibit the sale of a food in the market place simply because it is not in sympathy with its use. But the Government's position is clearly untenable. The provisions of the Federal Food, Drug and Cosmetic Act did not vest in the Food and Drug Administration or any other federal agency the power to determine what foods should be included in the American diet; this is the function of the marketplace."

Petitioners respectfully submit that the ruling in the instant case affects the entire dietary supplement and drug industry in invoking serious prohibitory restraints in the sale of products without legislative mandate.

4. Another question presented herein involves the jurisdiction of the Federal Food, Drug and Cosmetic Act. The issue is whether the Food, Drug and Cosmetic Act creates jurisdiction over any statement in a company's literature, or whether said Statute pertains solely to statements involving the nature, composition, proper use or value of a product. This is a recurring question which also involves the distinction between the jurisdiction under the Federal Trade Commission Act and the Federal Food, Drug and Cosmetic Act.

This question has occurred in the past and has not been ruled upon by this Court. (*U. S. A.* v. *Various Articles of Drug* * * * *Stanack Sales Co., Inc.,* U. S. District Court

of New Jersey, (1963) (unreported); *U. S. A. v. Various Articles of Drugs * * * Kaybel, Inc.*, United States District Court, District of New Jersey, (1963) (unreported) affirmed without ruling upon this question; *U. S. A. v. Various Articles of Drugs * * * Stanack Sales Co., Inc., Kaybel, Inc.* and *William B. Mandell*, 332 F. 2d 286 (Third Circuit 1964).

5. The final question herein presented involves the application of Section 502(f)(1) of the Statute [21 U. S. C. 352(f)(1)].

This issue involves the applicability of the Statute to misbrand a product for alleged inadequate directions for use premised upon the representation created in the purchaser's mind from a reference to certain ingredients in the product. In the instant case, the reference to certain ingredients as "lipotropic factors" was held to constitute a representation to the consumer that the product was being sold to treat liver diseases.

Petitioners respectfully submit that the Court below was in error. The application of this ruling would misbrand numerous food products and dietary supplement products contrary to the intent and purpose of the Statute. Lipotropic factors are ingredients which are found in our foods and were included in the instant product, together with vitamins and minerals as food supplements. The theory adopted by the Courts below is that since lipotropic factors are substances which affect the mobilization of fat, particularly in the liver, the mere reference to the words lipotropic factors creates a representation in the consumer's mind that the product is being sold to treat liver diseases.

This ruling, if it is correct, would misbrand numerous food products and dietary supplement products because

of the fact that such products are sold as foods and dietary supplements without attempting to sell them for any disease or drug purpose. Thus, many breakfast cereals, including Kellogg's "K" would be misbranded, because they list various vitamins contained in the products, but do not list the series of conditions for which these vitamins are useful.

Petitioners respectfully submit that these questions should be resolved and that settlement thereof is in the public interest. These questions involve recurring problems of regulation in the food, drug and cosmetic industry and should be settled, particularly where conflicts exist between the Circuits and between different regulatory agencies. We are considering broad and sweeping prohibitions not authorized by Statute, but which very directly affect the freedom of business and the freedom of the individual in his purchase and choice of products.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

MILTON A. BASS,

SOLOMON H. FRIEND,
Counsel for Petitioners.

Dated: August 23, 1965.

APPENDICES

APPENDIX A

Opinion

UNITED STATES DISTRICT COURT

District of New Jersey

Civil No. 875—60

UNITED STATES OF AMERICA,

Libelant,

v.

An undetermined number of shipping packages • • • labeled in part: • • •

"Vitasafe Formula M"
"Vitasafe Formula W"
"Vitasafe CF"
"Vitasafe Queen Formula with Royal Jelly Supplement for Women"

etc.,

Claimant.

Appearances:

David M. Satz, Jr., Esquire, United States Attorney for the District of New Jersey (by William E. Brennan, Esquire, Attorney, Department of Health, Education and Welfare) for Libelant

Bass and Friend, Esquires, New York City (by Milton Bass, Esquire) for Claimant

LANE, *District Judge*:

This action, which arises under the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. §§301 et seq., was initiated by the government's filing of a libel of information in this court wherein the United States, having seized a quantity of vitamin and mineral capsules and labeling for the articles located at Middlesex, New Jersey, under powers granted the United States by 21 U. S. C. §334, sought to have these articles condemned. The items were in the possession of the Vitasafe Corporation, Division of Consolidated Sun Ray, Inc., and also in the possession of the United States Post Office after delivery for shipment in interstate commerce. The asserted ground for seizure was that the designated articles were misbranded within the meaning of 21 U. S. C. §§343(a), 252(a), and 352(f)(1). The items were concededly introduced into and traveling in interstate commerce within the meaning of the act.

Pursuant to monition, there were seized at the Vitasafe Corporation's premises 906 packages containing Vitasafe capsules, and approximately 3,730,000 pieces of written, printed, and graphic material designed to promote the sale of the Vitasafe capsules.

The libel was amended to specifically include the products "Vitasafe CF" and "Vitasafe Queen Formula with Royal Jelly Supplement for Women," by name, which were found at the premises of Claimant when the monition was executed. A further amendment was allowed pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, so as to include the allegation that the seized articles were misbranded while held for sale after shipment in interestate commerce, as well as when introduced into and while in interstate commerce.

The United States alleges that the Vitasafe capsule, *as an article of food* within the meaning of 21 U. S. C. §321(f), is misbranded under 21 U. S. C. §343(a) in that:

I. Its labeling, when viewed as a whole, represents, suggests and implies that the nutritional needs for men and women differ, and that the "Formula M" capsules are designed to satisfy the special needs of men as contrasted to the "Formula W" capsules which are designed to satisfy the special needs of women, which representations, suggestions, and implications are contrary to fact;

II. The listing on the label of, and references in the labeling to, certain ingredients implies and suggests that the nutritional value of Vitasafe capsules is enhanced by the presence of such ingredients, when in fact such implications and suggestions are false and misleading in that the presence of these ingredients is of no nutritional significance for dietary supplementation. The ingredients so listed are: Vitamin K (menadione), rutin, lemon bioflavonoid complex, monopotassium glutamate, l-lysine monohydrochloride, dessicated liver, sodium caseinate, leucine, lysine, caline, histidine, isoleucine, phenylalanine, threonine, tryptophane, maganese, potassium, zinc, magnesium, sulfur, calcium, and phosphorous.

III. The statements in the labeling to the effect that the quoted "Minimum Adult Daily Requirements" (MDR) are a recommendation of the Food and Nutrition Board, National Academy of Science—National Research Council, are false and misleading because the Food and Nutrition Board has not recommended any "Minimum Daily Requirements" but has established "Recommended Dietary Allowances" (RDA) which differ from the MDR and are not the allowances designated in the labeling as the "Minimum Daily Requirements."

IV. The overall impression suggested and implied by the statements in the labeling concerning the large amounts of common foods that must be consumed in order to furnish quantities of nutrients equal to the quantities of such nutrients present in one Vitasafe capsule is false and misleading since such large quantities of food would not be needed to supply the necessary dietary requirements for these nutrients and since the labeling does not list all the various nutrients furnished by the stated quantities of food designated in the labeling.

It is further alleged that the Vitasafe capsule, *as a drug* within the meaning of 21 U. S. C. §321(g) is misbranded under 21 U. S. C. §352(a) in that:

V. Its labeling contains false and misleading representations, suggestions, and implications that the article is an adequate and effective treatment for depression, tension, weakness, nervous disorders, lethargy, lack of energy, lassitude, impotence, aches and pains, aging, impaired digestion, loss of appetite, skin infections, lesions and scaliness, night blindness, photophobia, fatigue, headache, insomnia, diarrhea, edema of the legs, hypersensitivity to noise, swelling, redness, soreness and burning of the tongue, impairment of memory, inability to concentrate, dermatitis, cracking of the lips, lesions at the corners of the mouth, growth failure in children, sore, swollen and bleeding gums, defective calcification of the bones, lowered resistance to disease, lowered vitality, which, representations, suggestions, and implications are false and misleading since the article is not an adequate and effective treatment for the disease conditions and symptoms as stated and implied.

VI. Its labeling contains false and misleading representations, suggestions, and implications that practically

everyone in this country is suffering from or is in danger of suffering from a dietary deficiency of vitamins, minerals and proteins which is likely to result in specific deficiency diseases, such as scurvy, as well as a great number of non-specific symptoms and conditions, which threatened deficiency is represented as being due to loss of nutritive value of food by reason of the soil on which the food is grown, and the storage, processing, and cooking of the foods, which representations, suggestions, and implications are false and misleading since they are contrary to fact.

It is further alleged that the article was misbranded within the meaning of 21 U. S. C. §352(f)(1) in that its labeling fails to bear adequate directions for use of the article as a "lipotropic factor" which it is represented to be.

Claimant denied the essential allegations of misbranding and moved for the dismissal of this action on the grounds that the large amounts of promotional material seized pursuant to monition were illegally seized since they do not constitute "labeling" within the meaning of the act.

This court has held that the approximately 3,730,000 pieces of written, printed and graphic matter are labeling within the meaning of 21 U. S. C. §321(m) and were properly sized. The memorandum opinion dated April 16, 1962, setting forth this decision is incorporated by and made a part of this opinion.

The issues before the court as defined in the pretrial order and as argued at the trial are:

(1) Does the labeling of the seized *res* make the representations, suggestions, and implications as alleged in the amended libel of information?

(2) Are any of these representations, suggestions, and implications false or misleading in any particular within the meaning of 21 U. S. C. §§343(a) and 352(a)?

(3) Does the labeling of the seized article bear adequate directions for use of the article as a "lipotropic factor" as required by 21 U. S. C. §352(f)(1)?

The evidence adduced at trial consisted wholly of real proof and expert testimony. The real proof offered by the government was extensive. It consisted of some forty-seven samples of literature seized which, together with the vitamin capsules, constituted parts of claimant's integrated sales and distribution program. The exhibits are, for the most part, elaborate advertising circulars directed to the general public and correspondence to prospective or present customers. They proclaim the various asserted virtues of the Vitasafe product, and are often accompanied by pictures representing the plight of vitamin-deficient sufferers before Vitasafe, the happy results of the Vitasafe treatment, doctors presumably in wholehearted agreement with the claims made, the capsules themselves, and like subjects.

Also offered as proof were four plastic canisters containing vitamins, on the exterior of which appear a list of "ingredients" and minimum daily requirements of same, along with the name of the product, the corporation distributing it, number of capsules contained, et cetera.

The prime evidence offered by both parties was the testimony of experts whose function was to assist the court in establishing the character of the labeling's impression on those who read it, the truth of the labeling thus understood, and the adequacy of the directions for use of the product as a "lipotropic factor." A careful evaluation of this expertise is necessary for the proper determination of this case.

The first witness called by the government was Gottfried M. Hochbaum, Chief of the Behavioral Science Section of the United States Public Health Service, a psychologist by profession.[1] Dr. Hochbaum's area of expertise may be generally described as the relationship between public relations and public health. He explained his work thus:

> "Some of our research was designed to identify factors which determine under what conditions people will or will not do certain things about their health as recommended by physicians, for example, why patients may not follow a doctor's prescription as to diets, toward exercises and other things; why people would or would not, and under what conditions people turn to a physician to help or other sources, pharmacists, neighbors, or anyone else. So, much of our research has dealt with identifying such factors.
>
> "Other research focused on communication, particularly communication in the health area. That is, how do people acquire information or misinformation in the health area, how do they develop certain habits from brushing their teeth to certain nutritional habits and others.
>
> "And thirdly, we have carried out research on how this knowledge can be translated in improving the education of the public in the health area, which involves communication, change of attitudes and habits, and so forth."

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[1] B.A., American University, Washington, D. C.; M.A., George Washington University, Washington, D. C., Ph.D., University of Minnesota. Employed by United States Public Health Service, 1952-date. Many periods of service with committees inquiring into public health and the behavioral sciences.

Dr. Hochbaum is eminently well qualified to testify to the type of consumer at which Vitasafe's advertising was directed and to give an expert opinion on the content of the labeling, as it is understood by these people.

Dr. Hochbaum characterized the various forms of advertising engaged in by claimant company as material which would probably be discarded by people with a reasonable amount of intelligence and education. But, on the other hand, it would be read by people who are in the low socio-economic level; people in the habit of reading pulp magazines of the "True Love Stories" variety. He notes that these magazines use the same type of pictures and headlines in the same style as used in subject advertising material. It is the doctor's opinion that the type of woman who reads these pulp magazines would, upon examining the advertising material here in evidence " * * * identify with the women in these pictures, * * * immediately connect [the problems illustrated in the advertising] with their own problems, because that is the way they have been used to reading these stories. They would immediately see in those headlines some of the problems they, themselves, experience, frustrations, marital problems, and so forth. A lot of these features would attract their attention and arouse their interest in reading on."

Dr. Hochbaum, in answer to a question of the court, agreed that he was referring to material like C-1 of Exhibit G-1 wherein is displayed five headlines with pictures of a girl or a girl and a man. One reads, "I couldn't stop torturing him," and another, "Our fights have turned to kisses." There is also a picture of a couple, presumably husband and wife, he being stretched out on a couch. The headline is, "I'm worried * * *. My husband's idea of a good time—sleeping all day Sunday."

The doctor testified:

> "* * * I believe that this kind of material would arouse the interest of many people who suffer from real or imaginary complaints, these vague variety of complaints such as tiredness, nervousness, real or imaginary, sexual impotence, marital problems, and so forth, because many of these people with little education who are very naive cannot identify the causes of their difficulties, and because they cannot * * *, they look for some magic formula, something that will change their lives and satisfy all their needs and remove their frustrations, so they turn to something like this with the real hope that this would provide a solution to their problems. And everything in here is in the form that would appeal to exactly this kind of people, attract these kinds of readers."

In evaluating the very many ailments that defendant's advertising lists under "Some Examples of What Lack of Vitamins and Minerals Can Mean," Dr. Hochbaum stated that people who can be expected to read such material would begin to identify themselves with the various ailments listed. As they read down the list and come to symptoms which do not particularly fit them, they are likely to acquire an attitude of susceptibility to suggestion and say, for example, "Come to think of it, last week my tongue did feel a little swollen." Thus, they are caught in this net that is thrown out in the form of a listed multitude of symptoms. He stated that the advertising techniques used by defendant company are those employed in many similar fields and that in devising and using such techniques, psychologists and various market consulting firms may well have been employed.

Further, Dr. Hochbaum testified that Vitasafe's offer of different "plans" for men and women implied to the average reader, unequipped to know the truth of the implication, that the nutritional needs of men and women are significantly different and that different kinds of nutritional treatment are therefore required. In this context, moreover, the term "high-potency capsule" implies that the consumption of the products will effect marital adjustment in some positive way.

The second expert witness for the government was Milton Wight Taylor, Professor of Biochemistry and Chairman of the Department of Agricultural Biochemistry at Rutgers University since 1954.[3] He is a member of many professional societies and has authored some 50 technical papers in the field of nutrition.

Dr. Taylor's testimony was that the literal language of Vitasafe advertisement Exhibit G-1(H) asserts that the consumption of any one of four or five foods in the groups shown would provide the user with the amount of the listed vitamin contained in the Vitasafe capsules. But the average reader might well assume that all the food pictured must be eaten to provide the vitamin equivalents in his diet. And the witness stated that an individual who ate one selection of each of the groups of foods connected to a vitamin would receive a good deal more than listed in the capsule because many of the foods listed are sources of many other vitamins and minerals; that a consumer who is receiving by means of his regular diet the average value in any particular vitamin would be receiving no benefit from additional vitamins contained in

[3] B.A., Agricultural Chemistry, University of Massachusetts, 1925; M.S., Agricultural Chemistry, Iowa State University, 1927; Ph.D., Agriculture Chemistry, Iowa State University, 1930; Association with Rutgers University, 1930-date.

Vitasafe capsules; and that various vitamins listed in the advertising of claimant company, while essential in diets, show amounts so infinitesimal compared with the amounts contained in regular diets that the capsule ingredients could not possibly be of any benefit to consumers.

Dr. Taylor asserted that excessive vitamins over the minimum daily requirement are, at best, of no benefit and that adding additional amounts of water-soluble vitamins, vitamin B-2 for example, to a diet already containing adequate quantities of the vitamin, merely results in excretion of the excess. With reference to claimant company's advertising he states that Exhibit G-1 (H-1) depicts a quantity of carrots which would probably supply in the neighborhood of twenty to thirty times the requirement of vitamin A. But, carrots are not depicted in claimant company's advertising as a source of vitamin A, but rather as a source of vitamin E,—and yet carrots are not an outstanding source of vitamin E. In this connection, he states:

> "Almost without exception the foods contain other nutrients besides the ones which are shown in the exhibit. It is almost impossible to get foods which do not contain several nutrients. It is very difficult, when we are working with experimental rations, to produce such things. We can use things like starch or sugar and synthetic vitamins, minerals. We do not use natural foods, because they contain so many things."

The witness further stated that a vitamin capsule would provide nothing that is needed by the consumer if he is an average American eating average meals. Only if his diet were unusual and restricted, like an elderly person

surviving on little more than tea and toast, would the consumer materially benefit from a Vitasafe capsule.

Dr. Taylor examined Exhibit G-1(C-1), a portion of claimant company's advertising in which it is claimed that nutritional values are lost in the process of cooking, as much as 80% of certain vitamins being destroyed. While he agreed that there is some loss in cooking and processing, he said that this is not of great significance in American nutrition. He pointed out that most of the tables of food values have been worked out based on food values for cooked foods in which losses have already occurred and have therefore been taken into consideration.

Dr. Taylor, in explaining his position that a subscriber to Vitasafe products would in all probability receive no value at all in using them, testified:

> The Court: Do I understand your testimony, Doctor, that it is your opinion that if a member of the public responded to any one of these ads of Vitasafe that are on exhibit here and sent a check for $8.66, or whatever it may call for, $2.38, and received a bottle of Vitasafe tablets or a series of them and consumed one each day or as many as prescribed or suggested in the Vitasafe literature, that that person is in essence getting no value at all for the money sent to the Vitasafe Company?
>
> The Witness: I would say that is true of most people but I still say that there are some people who might be benefited, if they are on a poor diet or for some reason they have unusually high requirements.
>
> If I may enlarge a little bit, I look on this—and I think this is true of many nutritionists—as insurance. I have questioned some of my associates, and they say, "Yes, I take vitamins, even

> though I believe my diet may be adequate, as insurance. I don't take, perhaps, the full dose." So that I would have no complaint with a person taking vitamins of this nature as insurance, just in case. But the fact still remains that they probably are not doing any benefit.

In a discussion of tables listed as Recommended Daily Allowances and Minimum Daily Requirements, it was testified by the witness that both have considerable safety margins. But while three or four per cent of the population's diet would be below the MDR, some forty per cent is below the RDA. Thus, RDA and MDR are different, the RDA being estimated with a far greater safety margin.

> "I think the MDR is, again, a very conservative estimate. By that I mean people do not want to err on the side of setting the requirement too low. That they don't want to do. Therefore even these so-called minimum daily requirements have a margin of safety."

Dr. Taylor said that there is a slight difference in the nutritional needs of men and women, particularly in thiamin or vitamin B-1, since this is roughly proportional to the amount of energy, particularly carbohydrate in the diet. He notes, however, that in defendant company's advertising, the amount of thiamin in the Vitasafe capsules is the same in the men's formula as in the women's formula.

The next witness was Dr. Paul Gyorgy, an eminent physician and nutritionist, now chairman of the department of pediatrics, Philadelphia General Hospital, and

Professor Emeritus of Pediatrics, School of Medicine, University of Pennsylvania.[3]

Dr. Gyorgy testified that dietary allowances are not synonymous with requirements, but rather allowances that would be adequate for maintenance of food nutrition in essentially all the population of the United States. These are allowances designed to maintain good nutrition in healthy persons in the United States under current conditions of living and to cover nearly all variations of the requirements for nutrients in the population at large. They are meant to afford a margin of sufficiency above minimal requirements, and persons who do not receive them would not necessarily suffer from malnutrition.

With regard to nutritional needs for a normally healthy woman, as opposed to that of a normally healthy man, he stated:

> "The recommended dietary allowances make such difference, but related mainly to the lower average weight, size of the body, caloric intake, protein intake is lower, other considerations of the food generally are not lower, and during the child-bearing age, the iron intake is slightly higher, but otherwise there is no difference."

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[3] Educated in Hungary, at University and Medical School; Professor of Pediatrics, University of Heidelberg; Research Fellow at Cambridge University, 1933-1935; Associate Professor, Western Reserve University Medical School; Professor of Pediatrics, University of Pennsylvania Medical School. 1955-1957. Consultant to Surgeon General of the Army. World War II-present. Member and past president, American Institute of Nutrition. Winner of many awards in field of nutrition. American Medical Association awards six "Paul Gyorgy Fellowships" for medical students. Discover of riboflavin, vitamin B-2, vitamin B-6 and co-discover of three other B vitamins. Author of nearly 400 publications concerning nutrition in man.

And he states it would make no difference whether a man or a woman consumed the vitamin capsule that defendant company advertises as prepared for woman or that the company advertises as prepared for man. Defendant's capsules, in any form, would not have any effect in any normal person. This witness did not believe that healthy people ranging from young children up to people of old age need a vitamin supplement, and he would only recommend vitamins for young infants and for persons of old age who are not on the best diet, in addition to lactating or pregnant women.

In connection with defendant company's listing as ingredients in its product, bioflavonoid, rutin, sulfur, magnesium, zine, molybdenum, cobalt, copper, potassium and phosphorus, in the amounts given in the advertising put out by claimant company, he states emphatically that all are irrelevant since they are absolutely insufficient to correct or tend to correct any possible deficiency. Further, he is of the opinion that a layman cannot possibly diagnose in himself any vitamin, mineral or protein deficiency.

Dr. Victor Daniel Herbert, an associate in medicine and tutor in medical science at Harvard Medical School, was next called by the government.[4] He testified that the

[4] B.S., Columbia, M.D., Columbia University, College of Physicians and Surgeons, 1952. Specialist in internal medicine, emphasis: nutrition and hematology. Intern and assistant ward officer at the Walter Reed Army Medical Center, 1952-1953, Senior Research fellow of the New York Heart Association, one year. Fellow in hematology, Montefiore Hospital, New York, 1958-1959. Research assistant, Department of Hematology, Mount Sinai Hospital, New York, one year. Member, faculty in medicine at Harvard Medical School, to present. Research papers published: primarily related to vitamin B-12 and folic acid; also calcium metabolism and ascorbate metabolism. Work also with thiamin, riboflavin, niacin, and pyridoxine. (Publication total approximately 60 papers.) Diagnostician and attending physican at Boston City Hospital in connection with particular diagnostic and therapeutic problems.

likelihood of various complaints referred to in claimant company's literature being due to a vitamin or mineral deficiency is infinitesimally small. Thus, he stated as to complaints such as depression, tension, weakness, impaired digestion, dermatitis, night blindness, photophobia, headaches, insomnia, diarrhea, swollen, burning tongue, impairment of memory, cracking of lips and lesions at the corners of the mouth, growth failure in children, sore, swollen and bleeding gums, impotency, edema of the legs, that there is little likelihood in America of their being caused by vitamin or mineral deficiency.

Dr. Herbert stated that a "lipotropic factor" is a substance involved in the body's mobilization of fat, primarily in the liver, and, in his opinion, there is no normal need to supplement the human diet with any lipotropic factor. Further, for an individual to determine whether he has a liver ailment and the extent of it, he would require at a minimum four years of medical school training and a liver biopsy. Dr. Herbert's testimony was similar with regard to the cause of sore, swollen, or bleeding gums and tumors of the brain, and the training needed to determine whether or not such conditions resulted from vitamin deficiency.

Dr. Herbert was asked whether three or four per cent of the American population have a deficiency of vitamins as measured by the minimum daily requirements. He answered:

> "I think it is quite possible that three or four per cent of a population may be ingesting less than the MDR of one or more of the vitamins listed here. However, in studies on this point which have been conducted indicating such a percentage, it has not been established that that amount less than the MDR resulted in a vitamin deficiency, because the

MDR actually is in excess of need. It is generally accepted minimal safe dose, rather than absolute minimum.

"When all the cases of vitamin deficiency reported in the United States in a single year are added up, they do not reach the figure of 20,000, and therefore the clinically ascertainable incidence as manifested by published reports is much less than 1 per cent; 20,000 projected into a figure of 180,000,000."

Attorney for claimant first called Dr. Harold Yacowitz, a nutritionist[5], who testified that we do have a problem with vitamin deficiency in the United States; that in general about forty to fifty per cent of the population does not meet the daily recommended allowances; and that some three or four per cent of the population would, in his opinion, fall in the category of actually suffering from nutritional deficiencies to a dangerous degree. He stated that the primary reasons for problems in nutrition are: (1) lack of knowledge of nutrition; (2) poor dietary habits among teenagers; (3) food faddism among women;

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[5] B.S., M.S., Ph.D. in nutrition, Cornell University. Over forty papers in the field of nutrition, only one of which relates to human nutrition, his particular specialty being experimental research in nutrition with animals, primarily poultry. Four years Associate Professor of Health Education, Ohio State University. Presently teaching course in health education at Fairleigh Dickinson University. Four years in charge of nutritional research for Squibb Institute of Medical Research, New Brunswick. One and one-half years Director of Applied Research for the Nopco Chemical Company, as well as a year as a research biochemist at Parke-Davis. Membership in various chemical and nutrition societies. Main area of work: animal feeding. Sample publications: *Vitamin B-12 Studies With the Hen; Some Effects of Growth Hormone Preparations in Pullets and Mature Hens; Antibiotic Levels in the Digestive Tract of the Chick; A Comparison of Growing Rations for Turkeys Reared in Confinement.*

(4) increased longevity; (5) dental problems in older people; and (6) loss of vitamins in food preparation and cooking.

Dr. Yacowitz, in reviewing subject labeling, states that the symptoms listed in relation to vitamin deficiency such as skin infection, lesions of the skin, rough, dry skin, nutritional night blindness and sensitivity to bright light, are recognized symptoms by experts in the field and that the taking of a Vitasafe capsule each day would afford some protection to a person against the occurrence of such symptoms.

With reference to claimant labeling which shows plates of food in connection with various types of vitamins, the doctor testified that it is worded in the disjunctive; any of the foods listed—not all of them—would match the Vitasafe capsule's content.

Dr. Yacowitz expressed the opinion that there is a difference in the nutritional needs between men and women, the difference being largely in the requirements of vitamin B.

On cross-examination, when asked to testify regarding the extent of work he has done personally in the area of research on the state of nutritional well-being of the American today, the witness answered that his experience on nutritional surveys had been minimal, and he based most of his statements on the work of authorities in the field. He subscribes to the accepted principle that generalization of nutritional survey findings as a basis for vitamin supplementation of healthy individuals is improper. It is necessary for a physician to evaluate each person individually, and that correction of an inadequacy should then be instituted, preferably by means of proper diet, although supplements by vitamin may be necessary

until dietary adjustments are made and the body stores repleted. Finally, he expressed the opinion that, as a nutritionist, the average diet of Americans takes care of any nutritional differences between men and women.[6]

Findings of Fact

A study of all the exhibits and the expert testimony outlined above leads this court to the following conclusions:

1. The labeling of the seized articles, when viewed as a whole, does represent, suggest and imply that a woman, because of sex alone, has different nutritional needs than a man, and "Vitasafe Formula W" will satisfy these special needs of women as contrasted to "Vitasafe Formula M" which will satisfy the special needs of men.

These representations are false and misleading since there is no difference in the nutritional requirements of non-pregnant, non-lactating women as compared to men, except for iron in women of childbearing age, which need is adequately satisfied by the normal diet readily available and normally consumed. With the exception of iron, nutritional need is the same for men and women. The quantities required for some nutrients differ depending on size, weight or activity, but this holds substantially true for both men and women. No reference is made in any of the labeling to conditions of pregnancy and lactation and any special need resulting.

With respect to iron content, both the men's formula and the women's formula contain the same quantity of

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[6] The defense also called Wallace L. Minto. It is abundantly clear from both direct and cross-examination that Mr. Minto is totally without qualification to testify as an expert on the issues presented here, and this court considers his testimony to be of no value whatsoever.

iron so that the "Vitasafe Formula W" and "Formula M" may be used interchangeably by either men or women with no difference in effect. All this is contrary to the implications of the labeling at issue.

2. The labeling of the seized *res*, when viewed in its entirety, does represent, suggest and imply that the nutritional value of Vitasafe capsules is enhanced by the presence in these capsules of the following ingredients in the stated amounts:

Vitamin K (Menadione)—.05 mg.

Monopotassium Glutamate—20 mg.

L-lysine Monohydrochloride—7 mg.

Sodium Caseinate (protein)—
100 mg. (Formula "M")
50 mg. (Formula "W")

Leucin—
8 mg. (Formula "M")
4 mg. (Formula "W")

Lysine—
7 mg. (Formula "M")
3.5 mg. (Formula "W")

Valine—
6 mg. (Formula "M")
3 mg. (Formula "W")

Histidine—
2.8 mg. (Formula "M")
1.4 mg. (Formula "W")

Isoleucine—
5 mg. (Formula "M")
2.5 mg. (Formula "W")

Phenylalamine—
4 mg. (Formula "M")
2 mg. (Formula "W")

Threonine—
4 mg. (Formula "M")
2 mg. (Formula "W")

Tryptophan—
1 mg. (Formula "M")
.15 mg. (Formula "W")

Managanese—5 mg.

Potassium—2 mg.

Zinc—.5 mg.

Magnesium—3 mg.

Calcium—
75 mg. (Formula "M")
50 mg. (Formula "W")

Phosphorous—
58 mg. (Formula "M")
39 mg. (Formula "W")

Choline Bitartrate—
31.4 mg. (Formula "M")
30. mg. (Formula "W")

Inositol—
15 mg. (Formula "M")
10 mg. (Formula "W")

Lemon bioflavonoid—5 mg.

Sulfur—22 mg.

Royal Jelly—550 mcg.

The evidence produced at trial proves that the normal or ordinary diet supplies amounts of the above-listed ingredients greatly in excess of those necessary for good nutrition. Furthermore, with the exception of the fat soluble vitamins A and D, vitamins ingested in excess of those required are excreted and make no nutritional contribution. The evidence further proves that the following ingredients represented to be present in the vitasafe product have no nutritional value whatever, namely rutin, lemon bioflavonoid, monopotassium glutamate, sulfur, choline bitartrate, inositol and royal jelly. Other ingredients, such as all the amino acids are in such small quantities as to be of no significant value when compared to the quantities of such ingredients which are required and which are present in the average diet. Because the ingredients here designated are either of no nutritional significance per se or are contained in the Vitasafe product in such minute quantities, these ingredients do not enhance the nutritional value of the Vitasafe capsules. Consequently, the representation and suggestion referred to in this finding is false and misleading.

3. The labeling of the seized *res* states and represents that the "Minimum Adult Daily Requirements" are a recommendation of the Food and Nutrition Board of the National Academy of Science National Research Council.

This representation is false. "Minimum Adult Daily Requirements" is a list of essential nutrients with designated amounts established by the United States Food and Drug Administration and set forth in their Regulations at 21 C.F.R. 125.3 (vitamins) and 125.4 (minerals).

The Food and Nutrition Board of the National Academy of Sciences has published its book, "Recommended Dietary

Allowances." This is a list of nutrients with specified amounts, which differ in the number of nutrients listed and the amounts of such nutrients from those set forth as "Minimum Daily Requirements."

4. Although correct if read literally and carefully, the labeling of the seized *res* represents and suggests to the ordinary reader that it is necessary to eat enoromus quantities and varieties of foods in order to obtain the variety of vitamins and minerals in the amounts provided by one Vitasafe capsule.

This representation is false and misleading because the variety and quantity of foods referred to in the labeling of the seized *res* provide many times the amounts of nutrients as well as additional nutrients than are supplied by one Vitasafe capsule.

5. The labeling of the seized *res* represents, suggests, and implies that Vitasafe capsules are an adequate and effective treatment of or preventive for the following symptoms and conditions which are referred to in this labeling: depression, tension, weakness, nervous disorders, lethargy, lack of energy, lassitude, impotence, aches and pains, aging, impaired digestion, loss of appetite, lesions and scaliness, night blindness, photophobia, fatigue, headaches, insomnia, diarrhea, edema of the legs, hypersensitivity to noise, swelling, redness, soreness and burning of the tonque impairment of memory, inability to concentrate, dermatitis, cracking of the lips, lesions at the corners of the mouth, growth failure in children, sore, swollen and bleeding gums, defective calcification of the bones, lowered resistance to disease, and lowered vitality.

This representation is false and misleading. The evidence produced at trial conclusively proves that the above

designated symptoms or conditions are caused by and associated with a great number of serious pathological diseases. Further, although some of these symptoms may be associated with vitamin and mineral deficiencies, the likelihood of their being caused by or associated with vitamin or mineral deficiences in the United States today is very small.

There is a danger involved in the use of this type of labeling insofar as a person having one or more of the above-listed symptoms may resort to a Vitasafe product as a cure. Such a person may continue taking this vitamin product for a long continued period, as he is urged to do in the labeling of this product, and thereby fail to obtain competent medical help to correct his physical illness.

6. The labeling of the seized article represents it to be of value because it contains "lipotropic factors." The evidence shows that such factors are substances which affect the mobilization of fat, particularly in the liver. Consequently, these factors are drugs within the meaning of 21 U. S. C. §321(g) in that their only known use is to affect the structure and function of part of the body. Further, the labeling of the seized article fails to bear adequate directions for use of Vitasafe as a drug within the meaning of 21 U. S. C. §352(f)(1). Nowhere in the labeling does there appear the conditions for which the Vitasafe capsule is to be used as a lipotropic factor or the collateral measures necessary for the safe use of Vitasafe by a layman as a lipotropic factor.

7. The article under seizure is both a food within the meaning of 21 U. S. C. §321(f) because its labeling recommends its use as and represents it to be of value as a dietary and nutritional supplement, and also a drug within the meaning of 21 U. S. C. §321(g) because its label-

ing recommends its use as and represents it to be of value as a curative or preventive of disease conditions in man affecting the structure and function of the body of man.

Conclusions of Law

1. This court has jurisdiction of this action under the provisions of 21 U. S. C. §334.

2. The *res* seized in this action is a food within the meaning of Section 201(f) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. §321(f) and is also a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. §321(g).

3. The approximately 3,370,000 items of written, printed, and graphic matter seized in connection with the Vitasafe products constitute labeling within the meaning of Section 201(m) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. §321(m). See memorandum of this Court incorporated by this case, *supra*, page four.

4. Section 403(a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. §343(a), decrees that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Section 502(a) of the same act, 21 U. S. C. §352(a) decrees that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular. Any single false, misleading, exaggerated, ambigious or over-emphasized statement or representation in the labeling of either a drug or a food misbrands the article within the meaning of either 21 U. S. C. §343(a) or §352(a).

5. Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. §352(f)(1), decrees that a drug shall be deemed to be misbranded unless its labeling bears adequate directions for use. Adequate directions for use requires that the labeling of a drug contains directions under which the layman can use a drug safely, intelligently, and effectively and for the purpose for which it is intended, including statements of all conditions, purposes or uses for which the drug is intended or for which it is recommended or suggested in its labeling or advertising; as well as the quantity of dose, frequency, duration, time, and route of administration and preparation for use.

6. Section 304 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. §334, provides, in part, that any article of food or drug that is misbranded when introduced into or while in interstate commerce or while held for sale, whether or not it is the first sale, after shipment in interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, in any district court of the United States within the jurisdiction of which the article is found.

7. The *res* seized in this action is misbranded as a food within the meaning of 21 U. S. C. §343(a) and as a drug within the meaning of 21 U. S. C. §352(a) because of false and misleading statements and representations in its labeling.

8. The *res* seized in this action is further misbranded as a drug within the meaning of 21 U. S. C. §352(f)(1) because its labeling fails to bear adequate directions for use.

9. The *res* under seizure was misbranded when introduced into, while in, and while held for sale after ship-

ment in interstate commerce, and must be condemned pursuant to 21 U. S. C. §334.

10. Libelant is entitled to a Decree of Condemnation and the articles of food and drug and the labeling under seizure shall be destroyed pursuant to 21 U. S. C. §334(d).

The Decree of Condemnation is granted with court cost, fees, storage and other proper expenses to claimant pursuant to 21 U. S. C. §334(e).

AMENDMENT TO OPINION FILED JANUARY 24, 1964

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

Civil No. 875—60

UNITED STATES OF AMERICA,

Libelant,

v.

An undetermined number of shipping packages * * * labeled in part: * * *

"Vitasafe Formula M"
"Vitasafe Formula W"
"Vitasafe CF"
"Vitasafe Queen Formula with Royal Jelly Supplement for Women"

etc.,

Claimant.

LANE, District Judge:

Amend opinion filed January 24, 1964, by adding footnote "1" at line 7 of page 5, after the word "decision," as follows:

1. In that opinion, rendered from the bench, we held *inter alia* that the Vitasafe advertising circulars seized by the government were labeling within the meaning of the Act, since used and designed solely for the purpose of increasing the sale and use of the product; a part of the integrated system of distribution used by claimant in marketing subject capsules. Physical proximity of the advertising to the product in question is not necessary for a finding that the advertising is labeling thereof. *United States* v. *8 Cartons, containing "Plantation* * * *,"* 103 F. Supp. 626 (W. D. N. Y., 1957), *United States* v. *353 Cases* * * * *Mountain Valley Mineral Water,* 247 F. 2d 473 (8th Cir. 1957).

Also, renumber all subsequent footnotes, now numbered 1-6, adding one to each.

ARTHUR S. LANE
Judge, United States District Court

Dated: February 5, 1964

MEMORANDUM OPINION

Civil Action 781-64

On Motion for Relief from Temporary Restraining Order

IN THE

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA

AGAINST

VITASAFE CORPORATION, a corporation, NUTRITIONAL QUALITY CONTROLS, INC., a corporation, THE DOLLAR VITAMIN PLAN, INC., a corporation, LIFE NUTRITION, INC., a corporation, INTERNATIONAL OIL AND METALS CORPORATION, a corporation, DR. PARKER MEDICINE COMPANY, a corporation, PHILIP S. VOLOSOV, an individual and Henry D. COHEN, an individual,

Defendants.

Appearances:

David M. Satz, Jr., Esquire, United States Attorney for the District of New Jersey (by Vincent J. Commisa, Assistant United States Attorney for plaintiff.

Herbert S. Alterman, for Defendant; Milton A. Bass, Esquire, Bass & Friend, New York City, appearing.

LANE, District Judge:

In an opinion filed January 24, 1964, *United States* v. *"Vitasafe Formula M. * * * "*, 226 F. Supp 266, this Court granted the government a decree of condemnation for certain vitamin products and advertising materials used in connection therewith, earlier held to constitute labeling therefor, 226 F. Supp at 269, footnote 1. The grounds for the decree were that the assertions contained in the labeling gave impressions to the user which were misleading and contrary to fact in violation of the Federal Food, Drug and Cosmetic Act, 18 U. S. C. §§ 301 *et seq.*, 226 F. Supp. at 278-279. The decree of condemnation was filed on April 10, 1964.

The Vitasafe Corporation, claimant in the condemnation suit, is one of a group of corporations, defendants in the present case, which distribute vitamins and similar products to the general public. Although the defendant companies are separate entities, they share officers and directors to a significant extent (see appended chart). Their mail order businesses are centered in the same place and conducted in the same manner by the same personnel. None of the companies manufacture vitamins; they repackage drugs which they buy in bulk and resell by mail. The style of their ads, customer service programs, vitamin containers, and other literature is strickingly similar. In short, while separately incorporated, all defendant companies are parts of the same operation and in substance are one.

	Samuel Josephowitz	David Josephowitz	Leon Potash	Henry D. Cohen	Adolf W. Goldscidt	Benjamin Oren	Arthur P. Silverstein	William H. Sylk	Harry S. Sylk	Benjamin Lerner	Leonard Joseph	Louis Robbins	Gordon Holt	Philip Volosov	Esa Calo
Director, V.S.*	X	X	X												
Officer, V.S.	X	X	X	X											
Director, Nut*					X	X	X								
Officer, Nut.					X	X	X								X
Director, $$*					X		X								
Officer, $$		X						X							
Director, Life*								X	X	X					
Officer, Life		X						X		X					
Director, I.O*	X	X									X	X			
Officer, I.O.		X	X	X									X		
Director, Dr. P*					X		X							X	
Officer, Dr. P*					X		X							X	

*V.S. = Vitasafe Corporation
Nut. = Nutritional Quality Controls, Inc.
$$ = The Dollar Vitamin Plan, Inc.
Life = Life Nutrition, Inc.
I.O. = International Oil and Metals Corporation
Dr. P = Dr. Parker Medicine Company

-3-

Since the signing of the condemnation decree, the Vitasafe Corporation has ceased its distribution of the series of circulars condemned. But Vitasafe has continued to service the clients which it had obtained prior to the decree. And the defendant corporations have continued the Vitasafe advertising campaign in their own names using circulars similar but not identical to those condemned in the Vitasafe action.

On August 17, 1964, the United States filed in this court a complaint for injunction against these six corporations and two individuals connected therewith. Pursuant to the complaint, the court issued a temporay restraining order on that date. The order restrained defendants, *inter alia*, from distributing or otherwise using literature which is objectionable under the condemnation opinion. It further specified a number of circulars which were not to be used.

The order also prohibited defendants from:

> Introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce any of the aforesaid articles which are addressed
>
> (a) to any persons to whom defendants have previously sent any of the items of written, printed, and graphic matter referred to in paragraph A (a) above,
>
> and (b) to any person who has sent to the defendants any of the order forms or order blanks which have been mailed by the defendants prior to the date of this decree or which have appeared in any newspaper, magazine, Sunday supplement or other advertisement prior to the date of this decree.

A hearing was held to allow a determination by this court of defendants' motion for relief from portions of the restraining order. The parties agreed that the court would consider together the motion for relief and the government's application for preliminary injunction.

I Injunction of Present Labeling

The government has established that both before and after the decree defendants used some material which would be subject to condemnation under the terms of the "*Vitasafe Formula M* * * *" opinion. An injunction will therefore issue prohibiting defendants from distributing any labeling which falls within the categories we have heretofore ruled misleading; specifically, labeling which when viewed as a whole:

1. Suggests or implies that a woman, because of sex alone, has different nutritional needs than a man, and that their product will satisfy those special needs.

2. Suggests or implies that the nutritional value of their product is enhanced by the presence in their product of certain listed ingredients.

3. States or represents that the "Minimum Adult Daily Requirements" are a recommendation of the Food and Nutrition Board of the National Academy of Science National Research Council.

5. Represents, suggests or implies that the product is an adequate, effective treatment of or preventative for a listed series of symptoms.

6. Represents the product to be of value because it contains "lipotropic factors" while failing to bear adequate directions for use as a drug.

The government also seeks provisions enjoining defendants from using specific pieces of literature in connection with their products. The ads and circulars complained of are similiar in style and content to those condemned, but are different from the earlier ones in significant detail. We think that under the circumstances, such an enjoining provision would be an unwise specification of the six general sections of the injunction indicated. If the government's contentions are sound, and it wishes to halt the use of these materials, it should do so under these broader terms. It would be premature and overhasty for us to decide now both the content of the injunction and the instances which will be held to fall within its terms. A fuller, more careful consideration of the facts than is here possible in the urgency of these injunction proceedings would be required to determine precisely which of defendant's statements do and which do not make the prohibited suggestions or implications. For that reason, the preliminary injunction should not contain a prohibition of the distribution and use of specific literature.

II Continuing Service to Past Customers

For several years, Defendant Vitasafe sought customers for its products through direct mail and "pulp" magazine advertising. The aim of this campaign was to enlist members of the public in one of the Vitasafe "plans" whereby a monthly supply of vitamins would be sent to the customer's home in return for monthly payments. It was this advertising which was, *inter alia*, the subject of the government's successful condemnation suit.

While the mailing of the offending materials by Vitasafe has been, we are assured, brought to a halt, the government seeks to enjoin Vitasafe and the other defendants

from further servicing accounts which were gained during the period of mislabeling.

The first asserted ground for this injunctive provision is that Vitasafe ought not to be allowed to enjoy the fruits of their wrongdoing; they ought not to enjoy a profit from customers wrongfully obtained.

This argument is unsatisfactory because it apparently misconstrues the thrust of the condemnation action under which the injunction is sought. That action was *in rem*; see *United States* v. *91 Packages * * * Nutrilite Food Supplement*, 93 F. Supp. 763 (D. N. J. 1950), and was brought against the advertising itself and not against the Vitasafe Company. It established only that said advertising was false and misleading. It did not and could not conclude that claimant was a wrongdoer. The character of Vitasafe's conduct in connection with the condemned literature was irrelevant to the action. *United States* v. *3963 Bottles * * *; Enerjol Double Strength*, 265 F. 2d 332 (7th Cir. 1959), *cert. denied*, 360 U. S. 931 (1959). We are therefore unable to draw a parallel between the case at bar and *United States* v. *United States Gypsum Co.*, 340 U. S. 76 (1950). There the Supreme Court said that wrongdoers in civil cases (in that instance, conspirators under the Sherman Act) could and should be restrained from capitalizing on past misdeeds. But there is nothing in the condemnation proceeding on which the injunction here is based which determines that Vitasafe is a wrongdoer. So the company ought not to be enjoined from continued client service on this ground.

The facts of this case suggest other, more tenable, grounds for the restraint. In the Vitasafe condemnation decree opinion, 226 F. Supp. 266 at page 269, footnote 1, we restated our opinion that the advertising circulars in question were labeling within the meaning of the Act. We said that it was labeling

> "since used and designed solely for the purpose of increasing the sale and use of the product; a part of the integrated system of distribution used by claimant in marketing subject capsules. Physical proximity of the advertising to the product in question is not necessary for a finding that the advertising is labeling thereof. (Citing cases.)"

The vitamin capsules and the literature were condemned solely because together they constituted mislabeled food or drugs.

Present consumers of Vitasafe products became customers as subjects of the condemned ads. Any vitamins sold by Vitasafe to such customers now is as much mislabeled by that advertising as if it had been sold to them before the condemnation decree. The discontinued circulars remain labeling for Vitasafe products in the minds of those previously subjected to it. This is the import of Judge Meany's decision in *United States* v. *46 Cartons * * * Fairfax Cigarettes,* 113 F. Supp. 336 (D. N. J. 1953).

The condemned labeling was the substance of a long and concerted campaign by Vitasafe. It is fairly inferrable from the facts that the vast majority of predecree customers were enticed into the Vitasafe net by false and misleading labeling. Furthermore, the literature which Vitasafe and its associate companies have used, of late, in connection with both old and new customers, innocuous though some of it may be, tends to reinforce, by similarity in content and form, the effect of the earlier mislabeling which stands condemned.

It is therefore our opinion that the condemned advertising mislabeled all Vitasafe products which were or will be sent to customers obtained prior to the decree. It is, necessary and proper in order to prevent further distribu-

tion of mislabeled vitamins to restrain and enjoin defendant Vitasafe's continued distribution to these customers.

Moreover, what Vitasafe may not do directly, it may not do through corporate sleight of hand. Any products sent by Vitasafe's alter-ego corporations to Vitasafe customers will be equally mislabeled by that company's pre-decree advertising, despite the fact that the name of the corporation on the bottom of the vitamin bottle may have been changed. It would be an empty gesture in this case to enjoin one and to allow the others to continue to perpetrate the prohibited acts. The closely related companies and individuals named in the complaint are therefore properly joined in this portion of the injunction.

Defendants suggest that this provision means "a company can be completely destroyed if at any time it is held there was a false or a misleading statement in its advertising." Not so! It is only under the circumstances of this case, where the condemned labeling was the core and substance of past business, that complete abstinence alone can provide a cure. The mere discontinuation of circulation which has taken place here will work at best an attenuation of the effects of the mislabeling. Under other conditions a far less drastic remedy might well be appropriate.

It must be emphasized that the purpose of this provision of the injunction is not to force the defendant corporations out of business. It does not "close down" the companies, but requires that they use properly labeled products. Its aim is the protection of the public, which has the right to be free not only from the condemned material itself, but the extended effects of the period of mislabeling.

The motion for relief from paragraphs B(a) and B(b) is denied. A preliminary injunction will issue identical to the temporary restraining order except that paragraph A(a) and references thereto will be deleted.

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 14964

UNITED STATES OF AMERICA

v.

AN UNDETERMINED NUMBER OF SHIPPING PACKAGES, ETC.

VITASAFE CORPORATION,

Appellant

No. 15066

UNITED STATES OF AMERICA

v.

VITASAFE CORPORATION, A CORPORATION, NUTRITIONAL QUALITY CONTROLS, INC., A CORPORATION THE DOLLAR VITAMINE PLAN, INC., A CORPORATION, LIFE NUTRITION, INC., A CORPORATION, INTERNATIONAL OIL AND METALS CORPORATION, A CORPORATION, DR. PARKER MEDICINE COMPANY, A CORPORATION, PHILIP S. VOLOSOV, AN INDIVIDUAL AND HENRY D. COHEN, AN INDIVIDUAL,

Appellants

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY.

Argued October 19, 1964

Before McLAUGHLIN, KALODNER and HASTIE, *Circuit Judges*

(Filed May 27, 1965)

KALODNER, *Circuit Judge*.

The District Court, in an *in rem* proceeding under the Federal Food, Drug and Cosmetic Act[1] (Appeal No. 14964), condemned and forfeited (1) some 900 seized packages of Vitasafe vitamin-mineral capsules, which it found to be "foods"[2] and "drugs"[3] introduced into interstate commerce, with "labeling" claims that were false and misleading, and with inadequate directions for their use;[4] and (2), approximately 3,730,000 pieces of written, printed and graphic material designed to promote the sale of the capsules, seized in the warehouse of the Vitasafe Corporation in Middlesex, New Jersey, which were held to be "labeling".[5]

The District Court, in a subsequent injunction proceeding (Appeal No. 15066), granted a Preliminary Injunction imposing restrictions on the defendants named therein with

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[1] 21 U.S.C.A. § 334.

[2] "Food" within the meaning of 21 U.S.C.A. § 321(f).

[3] "Drug" within the meaning of 21 U.S.C.A. § 321(g).

[4] In contravention of 21 U.S.C.A. § 343(a) and § 352.

Section 343(a) provides:

"A food shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular."

Section 352 provides in relevant part:

"A drug or device shall be deemed to be misbranded—

"(a) If its labeling is false and misleading in any particular.

* * *

"(f) Unless its labeling bears (1) adequate directions for use. . . ."

[5] 21 U.S.C.A. § 321(m) provides:

"The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

respect to the distribution of their products, their "labeling," and accompanying literature.

The critical issues presented by this consolidated appeal from the Condemnation Decree and Preliminary Injunction are:

(1) Were the District Court's fact-finding that the condemned capsules were misbranded "clearly erroneous."

(2) Did the District Court err in ruling that the 3,730,000 pieces of promotional literature seized in the warehouse of Vitasafe Corporation constituted "labeling".

(3) Did the District Court, in its Preliminary Injunction, abuse its legal discretion in imposing challenged restraints on the defendants' sale and distribution of its vitamin-mineral capsules.

The record discloses that the Vitasafe Corporation carried on a mail-order business for the sale of a vitamin-mineral dietary supplement. It purchased large quantities of vitamins from various manufacturers, and repackaged them under its own label at its headquarters in Middlesex, New Jersey. It thereafter sold to persons who responded to its advertising and promotional literature which appeared in magazines, newspapers and Sunday supplements throughout the United States. It also made sales to persons to whom it had mailed its promotional literature. It did not retain a record of persons to whom the literature was sent.

The Libel of Information alleged that the "labeling" which accompanied the Vitasafe product, a series of ten different pieces of promotional literature, falsely implied and suggested (1) that Vitasafe "Formula M" and Vitasafe "Formula W" were designed to satisfy the special nutritional needs of men and women respectively; (2) that

the nutritional value of the Vitasafe capsule was enhanced by the addition of several ingredients which were in fact of "no nutritional significance for dietary supplementation;" (3) that the minimum adult daily requirements of vitamins and minerals, specified in the "labeling", were the recommendations of the Food and Nutrition Board, National Academy of Science, National Research Council and (4) that large amounts of common foods would be needed to provide the nutrients supplied by one Vitasafe capsule.

The Libel also alleged that the "labeling" falsely and misleadingly implied and suggested that Vitasafe, as a drug, was an adequate and effective treatment for several common maladies; that practically everyone in the country was suffering from, or in danger of suffering from, a dietary deficiency of vitamins, minerals and proteins, which was likely to cause certain deficiency diseases; and that the deficiencies suggested were caused by a loss of nutritive value due to the soil in which food was grown, and the storage, processing and cooking of foods.

The Libel further alleged that the "labeling" represented Vitasafe to be "a lipotropic factor or agent" without adequately stating directions for its use as such.

The Government, in condemnation proceeding, presented several expert witnesses in support of its position. Vitasafe Corporation, as claimant, also presented expert witnesses.

The District Court, 226 F. Supp. 266 (D.N.J. 1964) found that Vitasafe was a "food" within the meaning of 21 U.S.C.A. § 321(f) because its "labeling" recommended "its use and represent[ed] it to be of value as a dietary and nutritional supplement;" that it was also a "drug" within the meaning of 21 U.S.C.A. § 321(g) because its "labeling" recommended "its use and represent[ed] it to be of value as a curative or preventive of disease condi-

tions in man affecting the structure and function of the body of man". It further found that the seized packages of Vitasafe were "misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce," in that their "labeling" was false and misleading,[6] and that there did not appear adequate directions for the use of Vitasafe as a lipotropic factor or agent.[7]

The District Court, on the basis of the stated fact-findings, held that the seized 900 packages of Vitasafe capsules were subject to condemnation as "misbranded", under 21 U.S.C.A. § 334, and so ordered. The record amply supports both the fact-findings and the order of condemnation with respect to these seized packages. It would serve no useful purpose to dwell on this aspect of this appeal in view of the exhaustive analysis relating to these packages in the District Court's opinion.

We are, however, of the opinion that the District Court erred as a matter of law in ruling that the 3,730,000 pieces of promotional literature seized while at rest in the Vitasafe warehouse in Middlesex, New Jersey, were "labeling" within the meaning of 21 U.S.C.A. § 321(m), and as such subject to condemnation under 21 U.S.C.A. § 334.

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[6] Although the District Court found that "labeling" to be false and misleading in almost every particular asserted by the Government it failed to find, without indicating its reason, that the "labeling" suggested that practically everyone in this country was suffering from, or in danger of suffering, dietary deficiencies which were likely to be the cause of a number of diseases, and that such deficiencies were caused by the soil in which food was grown and the storage, processing and cooking of foods; or that such suggestions were false and misleading.

[7] The District Court found that lipotropic factors "are substances which affect the mobilization of fat, particularly in the liver", and that "Nowhere in the labeling does there appear the conditons for which the Vitasafe capsule is to be used as a lipotropic factor or the collateral measures necessary for the safe use of Vitasafe by a layman as a lipotropic factor." 226 F. Supp. at page 278 (Para. 6, Findings of Fact).

The Government urges with respect to these 3,730,000 pieces that "all of the promotional matter seized was obviously intended to promote Vitasafe, and had no other useful purpose," and that "it supplements the label on the bottle of capsules, and was intended by the claimants to be ultimately used in the sale of Vitasafe," and thus it was "labeling" subject to condemnation under the Act.

The claimant, Vitasafe Corporation, does not deny the alleged intended use of the seized material, but contends that it was never actually employed for such purposes, and therefore could not have been subject to condemnation under the Act.

Under Section 321(m) the term "labeling" applies inter alia to "written, printed, or graphic matter" which appears upon any article or any of its containers or wrappers or "*accompanying such article.*" (emphasis supplied)

Section 331, 21 U.S.C.A. which prohibits, in subsection (a) "The introduction of delivery for introduction in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded", also proscribes in subsection (1) the use of "any advertising" matter thus used relating to the misbranded article. Section 334 provides for the seizure and condemnation of "labeling" as defined in Section 321(m).

Section 334(a) specifically provides that misbranded articles of food or drugs, "when introduced into or while in interstate commerce or while held for sale . . . after shipment in interstate commerce", may be condemned.

Critical here is the second clause "accompanying such article" in Section 321(m).

The 3,730,000 pieces of literature seized while in the Vitasafe warehouse cannot be categorized as "labeling" within the meaning of Section 321(m) since they perforce

cannot be held to have been "accompanying" any misbranded Vitasafe capsules "introduced into or while in interstate commerce or while held for sale . . . after shipment in interstate commerce" inasmuch as they never entered interstate commerce.

The cases cited by the Government in support of its contention that the 3,730,000 pieces of literature constituted "labeling" are inapposite.

In Kordel v. United States, 335 U.S. 345 (1948), "The alleged misbranding consists of statement in circulars or pamphlets *distributed* to consumers by the vendors of the products. . . ." Here there was never any "distribution" of the seized literature. (emphasis supplied)

In United States v. Urbuteit, 335 U.S. 355 (1948), certain machines misbranded as possessing "curative and therapeutic powers" were seized *after shipment in interstate commerce.* The claimant "admitted that the devices and leaflets [extolling the alleged virtues of the devices], *had been shipped in interstate commerce,* but denied that they were shipped together or that they were related to each other." (emphasis supplied)

In holding that the leaflets constituted "labeling" the Court said (pp. 357-358):

> "In this case it is plain to us that *the movements of machines and leaflets in interstate commerce* were a single interrelated activity, not separate or isolated one. . . . The fact that the false literature *leaves in a separate mail* does not save the article from being misbranded. Where by functional standards the two transactions are integrated, the requirements of § 304(a) are satisfied, though the *mailings and shipments* are at different times." (emphasis supplied)

Again, here both the machines and leaflets were introduced into interstate commerce.

In United States v. 47 Bottles . . . Jenasol, 320 F.2d 564 (1963) cert. den. sub nom. Schere d/b/a Jenasol Company v. United States, 375 U.S. 953, where we affirmed the condemnation of promotional literature, the latter had been *shipped in interstate commerce*—from New York to the State of Washington—to a distributor in whose home it had been found. The literature had been separately shipped to the distributor to promote the sale of a drug found to be misbranded.

Again, in United States v. Adolphus Hohensee, 243 F.2d 367 (1957), cert. den. 353 U.S. 976, where we affirmed the judgments of conviction for introduction of misbranded drugs into interstate commerce, the promotional materials and misbranded drugs had been *transported in interstate commerce.* Likewise, in United States v. 353 Cases . . . Mountain Valley Mineral Water, 247 F.2d 473 (8 Cir. 1957) the condemned literature, which extolled the medicinal and therapeutic qualities of a misbranded mineral water, had been *shipped,* along with the water, in *interstate commerce* from Hot Springs, Arkansas to Memphis, Tennessee, where both were seized.

We come now to the challenged sweep of the District Court's Preliminary Injunction at Appeal No. 15066.

The defendants in the injunction proceeding concede that if the District Court correctly held that the Vitasafe capsules were misbranded that it could enjoin its continuance. They contend, however, that the Injunction as issued is too broad in that, they say, (1) it enjoins sales of the capsules "even with proper labeling, to anyone who previously received any of the appellants' advertising literature and to any former customer", and (2) it prohibits

the distribution of literature "which contains certain specified statements and representations and then adds a clause 'or which is otherwise false and misleading' ".

In support of their first contention, appellants urge that "the Federal Food, Drug and Cosmetic Act does not authorize an injunction to prohibit shipment of a product, with proper labeling, on the ground that prior literature contained a false or misleading statement or misrepresentation"; that such a prohibition "is punitive in nature rather than remedial"; and that "it is unjust in that it will cause substantial, if not, total destruction of a company for any past false or misleading statement in its advertising."

In reply, the Government says, in substance, that the Preliminary Injunction, only restrains sales to "present customers" and that "There is no doubt that appellants can now market their product under appropriate labeling, to all the world—except those persons who have already been subjected to the false and misleading claims made by appellants."

The challenged provisions of the Preliminary Injunction enjoin the appellants from

> "B. Introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce any of the aforesaid articles which are addressed
>
> "(a) to any person to whom the defendants have previously sent, prior to the date of this decree, any written, printed, and graphic matter which makes any of the statements or representations set forth in paragraph A(a), or
>
> "(b) to any person who has sent to the defendants any of the order forms or order blanks which

have been mailed by defendants prior to the date of this decree or which have appeared in any newspaper, magazine, Sunday supplement, or other advertisement published prior to the date of this decree;"

The Injunction here was issued pursuant to Section 332(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 301 et seq., which provides in relevant part:

"The district courts of the United States . . . shall have jurisdiction, for cause shown . . . to restrain violations of section 331. . . ."

Section 331 provides:

"The following acts and the causing thereof are prohibited:

"(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

"(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce."

A food or drug is misbranded if "its labeling is false or misleading in any particular." 21 U.S.C.A. §§ 343(a), 352(a).

It is settled that the "high purpose" of the Act is "to protect consumers who under present conditions are largely unable to protect themselves in this field,"[8] and that the problem of its enforcement "is a practical one of consumer protection, not dialectics."[9]

[8] Kordel v. United States, 335 U.S. 345, 349 (1948).

[9] United States v. Urbuteit, 335 U.S., 355, 358 (1948).

In the leading case of United States v. Dotterweich, 320 U.S. 277, the late Mr. Justice Frankfurter, speaking for the Court, laid down these guidelines with respect to the Act's construction and application, at page 280:

> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."

In the instant case, the District Court, in its opinion reported at 235 F. Supp. 84 (D.N.J. 1964), specified the respects in which the "labeling" of the condemned capsules misbranded them and the record amply supports the specifications.

After so doing the Court said (pp. 88, 89):

> "Present consumers of Vitasafe products became customers as subjects of the condemned ads. Any vitamins sold by Vitasafe to such customers now are as much mislabeled by that advertising as if they had been sold before the condemnation decree. The discontinued circulars remain labeling for Vitasafe products in the minds of those previously subjected to it. . . .
>
> "The condemned labeling was the substance of a long and concerted campaign by Vitasafe. It is fairly inferable from the facts that the vast majority of pre-decree customers were enticed into the Vitasafe net by false and misleading labeling. Furthermore, the literature which Vitasafe and its associate companies have used of late in connection with

both old and new customers, innocuous though some of it may be, tends to reinforce, by similarity in content and form, the effect of the earlier mislabeling.

"It is therefore our opinion that the condemned advertising mislabeled all Vitasafe products which were or will be sent to customers obtained prior to the decree. It is necessary and proper, in order to prevent further distribution of mislabeled vitamins, to restrain and enjoin defendant Vitasafe's continued distribution to these customers."

It is clear from the foregoing that the District Court contemplated only enjoining sales of the capsules to those persons who had been subjected to, and inveigled by, the false and misleading claims made by the appellants in their directly mailed literature, and newspaper and magazine advertisements.

Under the facts in the instant case, and the applicable law, imposition of the restraints contemplated by the District Court would be well within permissible limits since a court may reasonably conclude that post-injunction sales of an article may be the end product of prior misbranding, and enjoin such sales.

However, the Preliminary Injunction, in Paragraph B, subsection (a) enjoins sale of the capsules "to any person to whom the defendants have previously sent, prior to the date of this decree, any written . . . matter" making specified false claims, irrespective of whether the sale is the end product of such "written matter", or the result of solicitation by proper post-decree literature.

That being so, we are compelled to the opinion that subsection (a) of Paragraph B of the Preliminary Injunction is beyond permissible limits and must therefore be vacated.

The restraints contemplated by the District Court may be satisfactorily achieved and made effective by adding the italicized clause "or will send" to subsection (b) of Paragraph B so that it will read as follows:

> "(b) to any person who has sent, *or will send,* to the defendants any of the order forms or order blanks which have been mailed by defendants prior to the date of this decree or which have appeared in any newspaper, magazine, Sunday supplement, or other advertisement published prior to the date of this decree;"

There remains for disposition the defendants' contention that the injunction is too broad in that, in Paragraphs A and C, it prohibits the distribution of literature which contains certain specified statements and misrepresentations, "or which is otherwise false and misleading". The defendants urge that the clause "otherwise false and misleading" enjoins acts which are neither "identifiable" nor "specific", and further fails to make "knowledge of falsity" a condition.

We are of the opinion that the defendants' contentions in this respects are valid, and that accordingly, the clause "or which is otherwise false and misleading" must be deleted from Paragraphs A and C of the injunction.

Rule 65(d), F.R.C.P. requires that "every order granting an injunction . . . shall be in specific terms. . . ." The challenged clause lacks the required specificity. It places the defendants "at the peril of a summons for contempt" without providing any guidelines for the carrying on of a future advertising program in a manner deemed appropriate by the District Court. Cf. National Labor Relations Board v. Express Publishing Co., 312 U.S. 426 (1941).

In closing, it must be noted that the District Court, in Paragraph A(a)(6) enjoined the defendants from shipping their product in interstate commerce when accompanied by "labeling" representing,

> "that practically everyone in this country is suffering from or is in danger of suffering from, a dietary deficiency of vitamins, minerals and proteins, which is likely to result in specific deficiency diseases such as scurvy as well as a great number of nonspecific symptoms and conditions, and that such threatened deficiency is due to loss of nutritive value of ordinary foods by reason of the soil on which the foods are grown, and the storage, processing and cooking of the foods,"

without a fact-finding that any such representations had been made in the past, or that they were false and misleading. It is apparent that the failure to make such a fact-finding was inadvertent since its basis is amply established by the record.

For the reasons stated the causes at Appeal No. 14964 and at Appeal No. 15066 will be remanded with directions to the District Court to vacate its Decrees respectively entered therein on April 13, 1964 and September 29, 1964, and to enter new Decrees in accordance with the Opinion of this Court.

A True Copy:

Teste:

Clerk of the United States Court of Appeals for the Third Circuit.

JUDGMENT

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 14,964

UNITED STATES OF AMERICA

v.

An undetermined number of shipping packages, individually addressed to consignees outside the State of New Jersey, each containing an article of food and drug, namely, capsules in vials, labeled in part:

(some shipping packages)
"Vitasafe Corporation 201 Lincoln Boulevard Middlesex, N.J." (with consignees name and address);

(some shipping packages)
"Distributed by Nutritional Quality Controls, Inc., Chestnut St., Middlesex, N.J." (consignees name and address) and coded in part "64M" or "64W"

(some vials)
"Vitasafe Formula M" and

(some vials)
"Vitasafe Formula W"

(some vials)
"Vitasafe CF"

(some vials)
"Vitasafe Queen Formula with Royal Jelly Supplement for Women"

and including, as labeling for the article, an undetermined number of items of written, printed and graphic matter, on the premises of the Vitasafe Corporation, Division of Consolidated Sun Ray Inc., 201 Lincoln Boulevard, Middlesex, New Jersey, namely:

(1) direct self-mailer (AS-VR) "You owe it to yourself *** 30 days free ***" and a Post paid postal card;

(2) One-page letter (NF1DHA-10K) beginning "Dear Friend: *** Further identified on bottom "This Is A Special Introductory Offer For New Members Only";

(3) One-page folder (NF-DHB-10K) reading in part on one side "Over a million people *** and on the other side "How the Vitasafe Plan saves you money while it helps to safeguard your health *** ";

(4) Certificate (V212) "Safeguard Your Well-Being the Proven Vitasafe Way";

(5) Leaflet (VSP-3A) "Important Facts You Ought to Know About Vitamin Capsules";

(6) Six-page letter (NF-VSP-E) "For more pep, increased energy, greater vitality . . .";

(7) Four-page letter (NF-VI-"W" or "M") "The Vitasafe Plan";

(8) One-page letter (NF-VN-H) "An Important Letter to Vitasafe Women";

(9) Four-page letter (RF/DB-6) "Our Gift to You"; and

(10) One-sheet (DBD-6) of four "Money-Saving 'Get Acquainted' certificates"

together with other items of written, printed and graphic matter used for the purpose of promoting the sale of the article.

VITASAFE CORPORATION

Appellant

(D.C. Civil No. 875—60

No. 15,066

UNITED STATES OF AMERICA

vs.

VITASAFE CORPORATION, a corporation, NUTRITIONAL QUALITY CONTROLS, INC., a corporation, THE DOLLAR VITAMINE PLAN, INC., a corporation, LIFE NUTRITION, INC., a corporation, INTERNATIONAL OIL AND METALS CORPORATION, a corporation, DR. PARKER MEDICINE COMPANY, a corporation, PHILIP S. VOLOSOV, an individual and HENRY D. COHEN, an individual,

Appellants

(D.C. Civil No. 781—64)

ON APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY.

Present: MCLAUGHLIN, KALODNER and HASTIE, *Circuit Judges.*

JUDGMENT

These causes came on to be heard on the records from the United States District Court for the District of New Jersey and were argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the Decrees of the District Court, respectively entered therein on April 13, 1964 and September 29, 1964, be, and the same are hereby vacated and the causes remanded for entry of new Decrees in accordance with the opinion of this Court.

ATTEST:

IDA O. CRESKOFF
Clerk

May 27, 1965

APPENDIX B

STATUTES

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.) provides in pertinent part:

SEC. 301 [21 U. S. C. 331]:

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703; or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j), or 507 (d) or (g), or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 506, 507, or 706.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506,

507, 704 or 706 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that approval of an application with respect to such drug is in effect under section 505, or that such drug complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any label-

ing requirement imposed by or under other provisions of this Act.

(p) The failure to register as required by section 510.

SEC. 302 (a) [21 U. S. C. 332(a)]:

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 301 of this title, except paragraphs (h), (i), and (j) of said section.

SEC. 403 (a) [21 U. S. C. 343(a)]:

A food shall be deemed to be misbranded—

If its labeling is false or misleading in any particular.

SEC. 403(i) [21 U. S. C. 343(i)]:

If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided,* That, to the extent that compliance with the requirements of clause (2) of this paragraph is impractical, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

SEC. 403(j) [21 U. S. C. 343 (j)]:

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the

Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

SEC. 502(f)(1) [21 U. S. C. 352(f)(1)]:

A drug or device shall be deemed to be misbranded—

If its labeling is false or misleading in any particular.

SEC. 502(f)(1) [21 U. S. C. 352(f)(1)]:

Unless its labeling bears (1) adequate directions for use.

REGULATIONS

The Code of Federal Regulations, Title 21, Part 125, provides in pertinent part:

SEC. 125.3(a)(2):

* * * . If the need in human nutrition for such vitamin has not been established, the label shall also bear the statement "The need for ..... in human nutrition has not been established," the blank to be filled in with the name of such vitamin.

APPENDIX C

United States v. Unknown Quantities . . . Honegar, Etc.

United States v. Unknown Quantities of an Article of Drug in Bottles of One Pint or One Quart Size, Labeled in Part: (Bottle Front Panel) "One Pint (or 'One Quart') Pure Honey & Apple Cider Vinegar * * * Honegar * * * (Back Panel) Use Honegar for Greater Zest in Drinks * * * Basting * * * Marinating * * * Salads * * * Vegetables * * * and Any Recipe Calling for Lemon and Brown Sugar", and Undetermined Number of Pieces of Written, Printed and Graphic Matter Accompanying the Article as Labeling * * * (B. T. Babbitt, Inc., Claimant).

In the United States District Court, Northern District of New York. No. 8010. Decided November 22, 1960.

Seizure—Disposal of Condemned Article—Sale After Change of Labeling—Effect of Past Labeling.—A honey and vinegar product seized and condemned for misbranding could be repossessed and sold, under Section 304(d) of the Act, when the claimant agreed to eliminate all references, in the labeling of the product, to the book *Folk Medicine* which advanced claims of medicinal qualities for honey and vinegar, despite government contentions that the product could not be legally sold as only a food because the public had already been impressed with the claim that the product had therapeutic value. The court stated that the public believes many food products have therapeutic value, but they can nevertheless be legally sold if no reference to such supposed value is made in the labeling of the products.

See FDC Act §304(d), Federal volume ¶2237,802.

For the defendant: Theodore F. Bowes, U. S. Attorney, Syracuse, N. Y., and William W. Goodrich, Asst. Gen. Counsel, Dept. of Health, Education and Welfare.

For the claimant: Ira M. Millstein of Weil, Gotshal & Manges, New York, N. Y.

MEMORANDUM DECISION

BRENNAN, J.: In the present phase of this proceeding, the claimant seeks the determination of this court that its proposed action in relabeling a condemned article constitutes a compliance with the provisions of the Federal Food, Drug and Cosmetic Act (21 U. S. C. A. 301-392). The problem is pointed up by a brief background of procedure and facts set out below.

[*Allegations of Libel*]

On March 21, 1960, the United States Attorney filed a libel which prayed for the seizure and condemnation of a food article known as "Honegar". The United States Marshal thereafter seized 5247 cases of bottles labeled with the trade name above and the same are now the subject of this proceeding. The libel in effect charged that the seized items were in violation of the provisions of the above mentioned Act in that same, considered as a drug, were misbranded. The particular provisions of the statute involved were 21 U. S. C. A. 352(b)(1), in that the label failed to bear the name and place of business of the manufacturer, packer or distributor and 352(f)(1) in that the label thereon failed to bear adequate directions for the use for which it was intended. B. T. Babbitt, Inc., filed a claim as the owner of the seized product and filed an answer denying the essential allegations of the libel. Thereafter upon the return day of the motion, claimant ap-

peared and consented that a decree be entered condemning the articles seized and requested that same be returned to the claimant to be brought into compliance according to the provisions of 21 U. S. C. A. 334(d). The United States opposed the release of said article and the court exercised its discretionary power in affording such relief. An order was thereupon entered containing the usual provisions requiring that a bond be filed by the claimant and that compliance should be under the supervision of the Food and Drug Administration. It was further provided "in the event relabeling cannot be agreed upon, and nothing in this order shall preclude the United States in the event relabeling cannot be agreed upon, from presenting proof, if any it has, that the background and past sales program make it impossible to bring it into compliance, as a food, with the Federal Food, Drug and Cosmetic Act".

[*Agreement to Relabel*]

The claimant then proceeded to negotiate with the Food and Drug Administration as to the steps to be taken to place the product in compliance with the law. These negotiations culminated in a letter by claimant to the Administration dated June 29, 1960 wherein the claimant agreed to completely relabel each of the bottles, copies of the new labels being submitted with the letter. All advertising and promotional literature, seized by the Marshal, was to be destroyed and no future reference would be made to the book "Folk Medicine" by Dr. Jarvis. The product was to be promoted and sold as a food product with no claim of therapeutic value. Same was to be marketed through claimant's sales force, food programs and food wholesalers. On August 18, 1960, claimant's proposal, as outlined above, was rejected by letter signed

by the Commissioner of Foods and Drugs. The bases of the rejections appear to be that the product was so connected with the contents of Dr. Jarvis' book, above mentioned, and the previous sales had been so advertised as to impress upon the public that claim was made that the product had therapeutic values to the extent that same could not be eliminated by the procedures proposed by the claimant. It was also urged that the Commissioner had determined that the product could not be successfully marketed limited as a food product. A hearing was held and evidence taken.

Brief reference should be made to the factual background which preceded claimant's attempt to market the product in question. It seems that the medicinal qualities of honey and vinegar were advanced and discussed in a book entitled "Folk Medicine" by Dr. Jarvis. This book was widely circulated and the offering of the product for sale by the claimant in its advertising and promotional literature leaned upon the statements contained therein. In effect, administrative determination rests upon the conclusion that the marketing of the product, through its advertising as a drug, constituted a fraud upon the public and that claimant's belated attempts to market same only as a food product are tainted with its past history.

There is little judicial precedent to guide the court in the matter of the decision required here. Without doubt the release of the product to the claimant for the purpose of bringing same into compliance with the Act is a matter of judicial discretion. Here was a perfectly good food product, without harm in itself or to its users, condemned essentially because of the advertising and promotional material used in connection with its sale. The discretion of the court was exercised in the light of the

purpose of the Act together with the principle that forfeitures are not favored.

While the decision of the administrative body deserves respect, the decision in *Buticaps Inc.* v. *U. S.*, 252 F. 2d 634 indicates that the ultimate judgment of the sufficiency of relabeling is the obligation of the court.

> "But the terms and conditions are to be fixed by the Court and not by the Department of Health, Education & Welfare. Libelee is entitled to judicial due process" (*Buticaps* v. *U. S., supra,* page 636).

[*Effect of Past Claims*]

Turning now to the merits, this court finds that the item involved is a food product. It is a mixture of honey and vinegar. Its components are plainly stated upon the proposed labels. The claimant has never been involved in previous similar law violations. Its good faith is not questioned. The libelant's contention that the article cannot be successfully sold as a food is an economic problem, the burden of which rests upon the claimant rather than upon the United States or the court. A similar product is presently marketed by at least two companies. That a segment of the public is impressed that a food product has certain therapeutic values is common to many food items in everyday use. The marketing of such items is within the law so long as baseless claims are eliminated therefrom.

All of the above leads to the finding and conclusion that the steps proposed to be taken by the claimant in its letter of June 29, 1960, together with the amendment which strikes the words "Fareham Farms" from the label and

substitutes the words "Sweet 'n Sour" brings the product into compliance with the law and the claimant is entitled to a judgment or order accordingly.

The authorities cited by the United States have not been overlooked but in general they apply to the exercise of discretion in the release of a condemned product to the claimant for the purpose of bringing same into compliance with the law rather than to the question which is involved here. An order or judgment may be submitted accordingly.